

REMARKS

A Final Office Action in the present application issued on January 22, 2007. Applicants replied on April 23, 2007. The reply was by way of amendment and argument, and further included a Declaration under 37 CFR §1.132 of co-inventor Timothy A. Ringeisen (hereinafter referred to as "the first Ringeisen Declaration"). An Advisory Action issued on May 11, 2007. Applicants' prior Amendment After Final appears to have been entered.

The instant response contains a second inventor declaration to supplement the first. Applicants respectfully submit that this Second Ringeisen Declaration is necessary. Specifically, the instant second affidavit is submitted for the purpose of providing the examiner with further information in the area of fluid dynamics. The Second Declaration was not presented previously because it was not anticipated that the examiner would have further questions for the inventor.

Accordingly, Applicants respectfully request that the Office consider the instant Ringeisen Second Declaration. Applicants furthermore respectfully submit that the evidence contained in the present Ringeisen Declaration, in conjunction with the previously tendered amendment and remarks, are sufficient to place the case into condition for allowance.

Claim Rejections – 35 USC §102/103

Claims 22-33, 38-45, 47-49, 51-53, 61-65, 74-77, 80-81, 84 and 87 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,158,574 to Stone (hereinafter referred to as "Stone"). Claims 22-30, 37-48, 51-65, 74-84 and 87 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Publication No. US2002/0127270 to Li (hereinafter referred to as "Li"). Claims 22-33, 36-65 and 74-87 were rejected under 35 U.S.C. §103(a) as being unpatentable over Stone in view of Li and further in view of U.S. Patent No. 6,428,576 B1 to Haldimann. Applicants respectfully traverse these rejections.

Stone discloses a biocompatible and bioresorbable structure for implantation into the knee joint which assumes the form and role of a meniscus. In one embodiment, the Stone fibers may be oriented substantially circumferentially by placing a slurry containing the fibers into a mold, a rotating the piston relative to the rest of the mold while compressing.

Li discloses a sheet membrane containing at least one layer of oriented biopolymeric fibers, such as collagen fibers. The Li method includes reconstituting biopolymeric fibers dispersed in a solution, placing the reconstituted biopolymeric fibers around a mandrel, rotating the mandrel to convert the reconstituted biopolymeric fibers on the mandrel into a tubular membrane of oriented biopolymeric fibers, cutting the tubular membrane longitudinally after it has been dried on the mandrel, rolling the cut membrane into a tubular form that is an inversion of the tubular membrane, inserting the rolled membrane into a tubular mesh, and

crosslinking the biopolymeric fibers to form a sheet membrane or oriented biopolymeric fibers.

The Action applied Haldimann primarily to show that the use of plasticizers and particulates in implantable bio-polymers was well known to the skilled artisan at the time of the invention.

Response to Advisory Action

The Advisory Action states that Applicants' arguments do not place the application in condition for allowance because:

Continuation of 11. does NOT place the application in condition for allowance because: While applicants state in their remarks and in the declaration that neither Stone or Li teach applicants claimed invention because the process to align the fibers of Li and Stone are different from applicants process to align the fibers, the alignment of the fibers is not caused by compressive forces alone (Stone is said to be oriented by the rotation, while Li is said to be oriented prior to compression) and the rotation disrupts any plate or layer formation, these remarks are not found persuasive by the examiner. Firstly as presently claimed the claimed invention is drawn to an implantable device not a process to form the implantable device, the only limitations expressed in some of the claims (such as 66) on how the product is produced is by a compressive force, a rotating mandrel or piston does apply a compressive force, therefore this limitation is considered met. Secondly the claims as currently amended do not preclude the possibility that the compression force cannot be supplied by either a rotating mandrel or piston. Thirdly since the claims are drawn to a product eg an implantable device the patentability is based upon the product itself not the process to produce the product. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Lastly while applicants have provided a declaration stating that the rotation of either the mandrel or the piston would disrupt any plate or layer formation there is no experimental evidence or showing by applicants that the processes of the disclosed references would not form partially aligned layers or plates, also the limitation that the fibers are at least partially aligned and express themselves in an architecture consisting of layers or plates is very broad and not found to be particularly limiting by the examiner. For these rejections the finality of the previous office action dated 01/22/2007 still stands..

In response, Applicants now provide the following remarks:

First, Applicants pointed out differences between the respective process steps only to explain why the respective articles were distinct from one another. More specifically, contrasts between the claimed and prior art processes were made to refute the assertion that the prior and instant processes were "substantially identical". See the Final Office Action of 1/22/07, page 3, lines 7-8; page 4, second complete paragraph; page 5, third complete paragraph; page 6, second complete paragraph; and the paragraph bridging pages 8 and 9.

Second, and in response to the position that the claims as amended do not preclude the possibility that the compressive force cannot be supplied by a rotating mandrel or piston, Applicants respectfully disagrees. Applicants submits that the statement in the prior Declaration "That the compression process of the instant invention never features a rotation of a piston or of the mold during the compression step" does in fact preclude this possibility. Though the claims do not expressly recite the absence of rotation, they cannot be interpreted to include rotation, in view of this statement by inventor Ringeisen.

Thirdly, Applicants agree that the claims are drawn to a product, and that novelty of the process by which the claimed invention is made does not guarantee patentability of the

resulting product. As stated above, the process steps were referred to in an effort to illustrate how the claimed invention differs from the cited art.

Lastly, and in response to the statement that Applicants have not shown any experimental evidence or showing by Applicants that the processes of the disclosed references would not form partially aligned layers or plates, Applicants' representative herewith submits another Declaration under 37 CFR §1.132 of co-inventor Timothy A. Ringeisen. This second Declaration provides a more detailed explanation as to why the products formed by the Stone and Li documents would not be in the form of plates or layers of fibers. In summary, Declarant Ringeisen states that points at different distances from the axis of rotation in Stone and Li will move or flow at different speeds ("differential flow"), and that this is what precludes the formation of plates or layers of fibers in Stone and Li.

Thus, neither Stone nor Li disclose or suggest the claimed invention. Further, Haldimann fails to remedy the deficiencies of Stone and Li. Thus, the claimed invention should be patentable over each of Stone, Li and Haldimann. Accordingly, Applicants respectfully request that the prior art rejections be withdrawn.

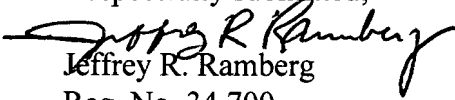
CONCLUSION

The alignment of fibers in Stone and Li is fundamentally different from the fiber alignment of the claimed invention. Specifically, the Stone and Li fibers do not align themselves in the form of plates or layers. This is due to processing differences, and specifically, differential flow in Stone and Li, a phenomenon not shared by the process used to make the instant fibrous articles.

In view of the above remarks, and the previously submitted amendments and remarks, Applicants respectfully submit that the instant application is in condition for allowance. Accordingly, Applicants respectfully request that the Office issue a Notice of Allowance directed to claims 22-26, 28-33, 36-50, 52-65 and 74-87.

Should the Examiner deem that any further action on the part of Applicants would be desirable, the Examiner is invited to telephone Applicants' undersigned representative.

Respectfully submitted,


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